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Enhancing Research Capacity for Global Health: Evaluation of a Distance-Based Program for International Study Coordinators

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Abstract

Introduction—Due to the increasing number of clinical trials conducted globally, there is a need for quality continuing education for health professionals in clinical research manager (CRM) roles. This paper describes the development, implementation, and evaluation of a distance-based continuing education program for CRMs working outside the United States.

Methods—A total of 692 applications were received from CRMs in 50 countries. Of these, 166 were admitted to the program in two cohorts. The program, taught online and in English, included four required and one optional course. Course materials were also provided as hard copies and on CDs. A pretest/posttest design was used to evaluate the outcome of the program in terms of changes in knowledge, participants' capacity-building activities at their research sites; and participant and supervisor perceptions of program impact.

Results—Participants demonstrated significant improvements in knowledge about clinical research, rated course content and teaching strategies positively, and identified the opportunity for interactions with international peers as a major program strength. Challenges for participants were limited time to complete assignments and erratic internet access. Participants offered capacity building programs to 5061 individuals at their research sites. Supervisors indicated that they would recommend the program and perceived the program improved CRM effectiveness and site research capacity.

Findings—Results suggest that this type of continuing education program addresses a growing need for education of CRMs working in countries that have previously had limited involvement with global clinical trials.

Keywords

International Research; Global Clinical Trials; Research Coordinator Education

Introduction

There are increasing numbers of clinical trials being conducted in "emerging research" regions outside of North America, Western Europe, and Oceana--the traditional sites for industry-sponsored clinical research. [1] A recent analysis of biopharmaceutical clinical trials

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registered in the ClinicalTrials.gov database revealed that 24 of 25 countries with the fastest rates of growth in clinical research (most of which were in Eastern Europe, Southern Asia, Africa, and Latin America) had not had significant involvement in research in the past.[1] Reasons for this shift are reduced financial and operational costs to sponsors, access to large patient populations, ease of overcoming regulatory barriers in developing countries, and lack of exposure to drugs or therapies that may interfere with evaluating new treatments. [2,3] This shift in location of clinical research sites creates challenges and opportunities related to the provision of continuing education for the research coordinators or managers who are critical to ensuring the success of studies and adherence to international guidelines for the conduct of quality research.

Clinical research managers come from a variety of professional backgrounds including nursing, medicine, psychology, social work, public health, or biomedical sciences.[4] In this paper we use the term “clinical research manager” (CRM) to refer to individuals who, regardless of title, assume primary responsibility for coordinating and implementing a clinical study.[4] The role of CRM includes responsibilities for developing study protocols; identifying appropriate research sites; hiring and managing members of the research team; ensuring compliance with ethical and other regulatory requirements; recruiting study participants; coordinating and managing project implementation including collection, recording, and storage of research data and specimens; and assisting with data analysis and dissemination of findings. [4–6]

Most CRMs learn their roles on the job and in educational programs that are fragmented and do not provide in-depth or comprehensive coverage of the multiple components of the CRM role. [4,7–10] Insufficient educational preparation presents challenges to assuring adherence to ethical standards and regulations stipulated by governmental and research funding agencies. [4,11] Although several authors have identified the need for comprehensive and coordinated educational programs for CRMs, there have been few studies evaluating the outcomes of such programs. Only two studies were found that specifically evaluated outcomes of CRM training programs. One study was an evaluation of three online distance education programs for international study coordinators.[4] Participants rated the courses and the teaching strategies positively, although narrative comments indicated challenges related to internet connectivity and having sufficient time to complete course requirements. The effect of the courses on participant knowledge or practice was not assessed. Taekman et al. [12] reported that 18 study coordinators who participated in an interactive simulation activity demonstrated improved confidence when comparing baseline to post-simulation scores, however there was no comparison of effects of training with and without the simulation activity. There is thus a clear need for further development and evaluation of quality continuing education programs for health professionals engaged in CRM roles.

The purpose of this article is to describe the development, implementation, and evaluation of a distance-based continuing education program for study coordinators working at sites outside of the United States. The project was funded by a “Challenge Grant” (subsequently named *Promoting Enhanced Research Capacity for Global Health or PERC*). from the U.S. National Institutes of Health (NIH) Fogarty International Center.[13] Evaluation questions were: (a) what are the participants’ and supervisors evaluations of the program?; (b) what are the participants’ evaluations of the courses that were taught?; (c) how much time did participants spend per week completing program requirements?; (d) what were the changes in knowledge about clinical research as measured by pretests and posttests administered before and after each course?; (e) what types of capacity-building activities were provided by course participants at their research sites, and how many participated in those activities?; and, (f) what were the reasons for early withdrawal from the program cited by those who did not complete the program?

Design and Methods

Design

The project used a pretest - posttest design and was approved by the Institutional Review Board at the University of Alabama at Birmingham. All prospective program participants completed an application that included a signature from their supervisors indicating support for their participation in the program, and all participants signed consent forms and returned the forms via email and/or fax to the Principal Investigator (LW). Applications were required in order to ensure that prospective participants met sample inclusion criteria.

Sample

A purposive sampling procedure was used to recruit CRMs working at sites outside of the United States by sending announcements about the program to a variety of contacts including research networks supported by the NIH with international sites, and other global contacts of the research team. Such networks included the HIV Prevention Trials Network, the Global Network for Women's and Infant's Health Research, the Global Alliance for Nursing and Midwifery, and the Pan American Nursing and Midwifery Collaborating Centers. The email announcement described the program, encouraged recipients to share the email with colleagues, and included an attachment with further information, application, and consent form. These announcements were sent at the end of September 2009 with a November 15 deadline for completed applications and signed consent form. This quick turn-around was due to the short time-line associated with the NIH Challenge Grant. The criteria for inclusion included: (a) current status as a clinical research nurse, coordinator, or manager; (b) having a nursing or medical degree, or a bachelor's degree; (c) access to the internet at least once per week to participate in course discussion board postings, email, and periodic audio chat conferences; (d) access to a computer with the specified capacity; (e) basic proficiency in English and computer skills including word processing and email; (f) commitment to complete all four courses required for the program, and disseminate lessons learned at their sites; and (g) letter of support for program participation from the immediate supervisor.

A total of 692 applications were received from 50 countries for 150 program slots. Priority was given to CRMs working at NIH-supported sites because the project was funded by the NIH. Priority was also given to CRMs who rated their level of English proficiency at least a 4 on a 5-point Likert scale (1=not at all proficient, 5 = extremely proficient), and represented a wide geographic distribution. One hundred sixty six applicants were selected for the 150 slots in order to allow for attrition. The program was offered to two cohorts of students over 2 years. The first cohort included 75 participants and the second cohort included 91 participants. A total of 60 of the first cohort and 70 of the second cohort participants completed the program, for an overall retention rate of 80%. Table 1 describes the demographic characteristics of the sample. The majority of participants were from Africa and Asia.

Intervention: Course Development and Implementation

The continuing education program, taught online and in English, included four required courses and one additional optional course that were adapted from courses originally developed for two previously-funded projects. Courses for those projects had been developed based on needs assessments of CRMs from 14 countries who were working at NIH-supported research sites. [4] The courses were offered via the Blackboard, Inc. (www.blackboard.com) online learning platform. In addition, all course materials (i.e. narrated PowerPoint presentations, assignments, and required readings) were recorded onto CDs and hard copies of written materials were placed in notebooks. The CDs, notebook,

course textbook, and a microphone headset were mailed to each participant in order to provide alternate sources of course content to students with limited internet access. In addition, faculty recorded podcasts to supplement the course materials, arranged optional synchronous online class discussions, and sent weekly cell phone text messages to participants who were able to receive free cell phone text messages. Participants were advised to allocate at least 4 hours per week for course assignments and have reliable internet access in order to post responses to course discussion boards at least weekly. EXHIBIT 1 lists the course titles, objectives, and the length of each course.

Courses were offered in three different sections of 25–30 students each, and each section was taught by a master's-prepared nurse with extensive experience as a CRM. Each course included a series of learning modules with specified objectives, learning activities, and resources such as articles, recommended websites or other internet-based resources; narrated PowerPoint presentations; podcasts; and team-building assignments to promote development of a learning community. Participants were required to take part in discussion board postings, internet-based chats and classes; and were expected apply lessons learned in the courses by providing workshops or classes to enhancing research productivity and capacity at their sites. Participants completed pretests and posttests for each course and had to achieve a minimum score of 70% on the posttest to progress. Teaching strategies were based on principles of adult learning and the framework proposed by Lock and Redmond for international online collaboration. [4,14] In order to ensure intervention fidelity across sections of each course offering, the co-investigator (MR) reviewed checklists completed by course instructors to ensure that each course topic was addressed and that instructors spent similar amounts of time on each topic.

Data Collection Methods and Measures

The program evaluation included participants' evaluations of the courses, teaching strategies, and overall program; changes in participants' knowledge levels measured by pre and post-tests of course content; participants' reports of capacity-building activities at their research sites; and supervisors' evaluations of the program impact. Standard course and teaching evaluation forms used at the University of Alabama at Birmingham School of Nursing were modified slightly to collect data on participants' evaluations of courses and teaching strategies. Each form included 17 items and students rated each item on a 5-point Likert scale. Additionally, participants reported how much time they spent each week on the course, evaluated the different teaching strategies, and provided narrative comments about course strengths, applicability of course topics to their research roles, and suggestions for improvement (Table 2).

A 21-item investigator-developed online survey was sent to participants following the completion of the program (see Table 3). Investigators developed tests to assess students' levels of knowledge about course content at the beginning and end of each course. The number of questions on each test ranged from 25 to 36 (Table 4).

Participants completed logs that summarized their capacity-building activities at their research sites and submitted these logs at the end of the fourth course. At the end of the program, supervisors received an email invitation with a link to an online anonymous survey developed by the investigators, which asked for their perceptions of the impact of the program on the quality of research at their sites. To determine reasons for participant attrition, participants who withdrew from the program were asked to complete an anonymous 10-item online survey that was developed by the investigators. All instruments that were developed for this study had face validity assessed by the members of the research team, although there were no assessments of reliability.

Data Analysis Procedures

Descriptive statistics were used to report findings related to participants' evaluations of courses, teaching effectiveness, and the overall program, as well as supervisors' evaluations of the program. Paired t-tests were used to assess changes in pre and posttest scores, with a p value of less than .05 considered significant. Quantitative data were analyzed using the PASW Statistics 17 software package. The NVivo 9 qualitative data analysis software was used to facilitate content analysis and identification of themes from the participants' course evaluations and capacity-building logs. Content analysis procedures were used to identify themes of the capacity-building activities described in these logs, and descriptive statistics were used to calculate the numbers of programs offered and the number of participants attending these programs.

Findings

Course, Teaching, and Overall Program Evaluation Data

Students rated both the course content and teaching strategies positively with mean scores ranging from 1.1–2.2 on the 5-point Likert Scale (with low scores reflecting more positive ratings). Participants reported spending an average of 4.9 to 6.1 hours per week on the three courses. A summary of themes that emerged from content analysis of narrative comments in the course evaluations (summarizing comments in evaluations of all four course for the Year 1 and 2 cohorts) is included in Table 2. There were significantly more comments in response to the question asking about positive aspects of the course (n=352) than the question asking about negative aspects of the course (n=205). The most frequently mentioned positive aspect was the opportunity for group interaction with students from other research sites around the globe. For example, one student commented: "*Sharing of experience and learning through other's experience. Could interact with students and learn their perspectives through the discussion forum. Also I like the networking that is happening during the course."* Students also identified specific aspects of course content and the course tools (e.g. the online platform, CD ROMs, notebooks, podcasts and text messaging) as positive aspects of the courses. The negative aspect of the program identified most often was lack of time to complete course assignments, since most students indicated that they were not given time off of work to complete the course requirements. The second most frequently identified problem was problems with internet access.

Table 3 summarizes the findings from the End of Program Survey completed by 91 of the 130 participants who completed the program. The mean rating of all items on the 4-point Likert scale ranged from 3.29 to 4.0, indicating that participants perceived the program to be very useful in enhancing their knowledge and skills, improving research capacity at their sites, and assisting them with meeting their individually identified learning goals. Participants viewed the distance learning strategies as effective and rated all strategies positively.

Of 34 students who withdrew early from the Year 1 and 2 cohorts, 8 completed the anonymous online survey sent to assess reasons for early withdrawal (24%). The main reason for withdrawing from the program was job workload (reported by 5 respondents) or personal reasons (reported by 3 respondents). Only three (37.5%) of the respondents indicated that they were given time at work to complete course requirements. Seven (87.5%) indicated that they felt that the program had been beneficial even though they had withdrawn.

Results from Pre and Posttests Measuring Knowledge of Course Content

Table 4 summarizes changes in pre and posttest scores for each of the four required courses for the Year 1 and Year 2 cohorts. Paired *t*-test analyses indicated significant improvements in scores from the pretest to the posttest for all four courses for both cohorts. The pretest-posttest differences ranged from 6.05 for the RC4 course in Year 1 to 24.09 for the RC1 course in Year 1.

Summary of Capacity-Building Activities of Students

Table 5 illustrates the 12 major themes identified in review of the participants' capacity-building logs, and the frequency with which each theme was reported. Participants described offering a total of 308 different capacity building activities to a total of 5061 individuals. Although some of these individuals may have participated in more than one educational program, the results indicate that there was a multiplier effect of the distance education program at the participants' sites.

Supervisor's Evaluations of the Program

Table 6 summarizes the data from supervisors' evaluations of the program. Despite two follow-up requests, survey responses were received from only 21 of 130 supervisors (16% response rate). Although supervisors had signed the participants' applications indicating that they supported program participation and understood they would be asked to complete an online evaluation at the end of the program, the program did not directly seek involvement from supervisors. This lack of involvement may have contributed to the low response rate, particularly for participants in the second cohort since it had been nearly two years from the time of initial contact with supervisors until they received the request to complete the online survey. In fact, several supervisors commented that they would have preferred more direct involvement in the program. Our limited data indicate that supervisors perceived the program as valuable in enhancing the participants' effectiveness as CRMs, and the research capacity at the sites. Supervisors indicated that they would recommend the program to others. They identified several program challenges or suggestions for improvement including: problems with internet connectivity, extending the program length to minimize the weekly time commitment, and individualizing the program to meet site-identified educational needs. Narrative comments addressed perceived program strengths included real-world applicability of the curriculum, enhancement of site research capacity, development of mentoring and teaching skills of the participants, and global networking opportunities.

Discussion

This study indicates that the program was effective in addressing the lack of integrated and comprehensive educational programs for CRMs as identified in the literature. [4,7–10] Although a number of authors have identified the need for systematic and coordinated capacity-building programs for CRMs, this study is one of only a few that evaluated such programs. Our findings reflecting high levels of student satisfaction but also problems with internet connectivity and time constraints were similar to those reported from our earlier studies. [4]

Results from the course, teaching, and overall program evaluations indicate that major strengths of the program included offering the material using a variety of modalities (online learning platform, CD ROM, notebooks, podcasts, and text messaging), and the opportunity for mentoring by instructors as well as interaction with other CRMs from around the world. This type of interaction and mentoring is not available in many other currently available programs offered online; instead, they are offered as independent study courses without the

opportunity for group interaction and mentoring. To further strengthen the program, simulation exercises may be included in future iterations, given Taekman et al.'s findings on the positive effects of interactive simulation exercises on study coordinator confidence levels.[12] Another strength of the program was the sharing of information acquired by course participants who provided capacity building activities to 5061 of their peers on a variety of topics related to clinical research.

The major challenges identified were the lack of time to complete course requirements and difficulty with internet access. Although the average number of hours spent by participants on the courses ranged from 4.9 to 6.1 hours per week, some participants spent considerably more time, possibly due to challenges if English was not their primary language. Another challenge, reflected in the low response rate by supervisors to the follow-up surveys, was the limited involvement of supervisors in the program.

The major limitations of this study were related to the use of convenience sampling and the use of a pretest-posttest design rather than a more rigorous experimental design. Time and funding constraints precluded the use of random sampling or an experimental design.

There is a great need and demand for this type of integrated continuing education program as evidenced by the number of applications received for the program despite relatively limited publicity and a short 6-week timeframe. Evaluation data from this study suggest that future programs should incorporate online teaching methods that promote sustained interaction among students and faculty, and address all components of the complex CRM role. Future program planners should consider involving supervisors and encouraging them to provide time during the work week for participants to complete course assignments. Supervisors should also be encouraged to provide access to high speed internet at the worksites so that students can participate easily in the interactive course discussions. There is a need for future research, using experimental designs, to evaluate the impact of this type of continuing education program on the actual conduct of research at study sites, and to compare the benefits of the type of interactive teaching strategies used in the PERC program with independent study online programs, using experimental designs. Outcome variables that would evaluate the impact on research might include assessments of the informed consent process, comparisons of the numbers of deviations from study protocols, and study participant recruitment and retention rates.

Online interaction among students from different countries offers valuable opportunities for students to learn from one another. Benefits of continuing education programs are enhanced when students provide capacity-building activities for their worksite colleagues. Using multiple teaching strategies helps minimize challenges related to limited internet connectivity when offering distance based courses to students at international sites. CRMs who have adequate preparation for their roles are critical to the success of clinical research, and there is a clear need for ongoing development and evaluation of comprehensive and integrated continuing educational programs that will prepare them for their roles.

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Lessons For Practice

1. Online interaction among students from different countries offers valuable opportunities for students to learn from one another.
2. Benefits of continuing education programs are enhanced when students provide capacity-building activities for their worksite colleagues.
3. Using multiple teaching strategies helps minimize challenges related to limited internet connectivity when offering distance based courses to students at international sites.
4. Many students need allocated work time and support of supervisors to accomplish program objectives.
5. Further research is needed to evaluate the effects of this type of continuing education on the quality of research conducted at participants' study sites.

Table 1

Demographic Characteristics of Participants

Cohort	**One (n=75)**	**Two (n=91)**
Gender: (number/%)		
Male	12 (16%)	23 (25%)
Female	43(57%)	61(67%)
Not Reporting	20 (27%)	7 (8%)
Professional Background (number/%)		
Nurse	34 (45%)	50 (55%)
Physician	14 (19%)	19 (21%)
Other	26 (35%)	8 (9%)
Not Reporting	1 (1%)	14 (15%)
Years Working in Clinical Research	(N=73)	(N=52)
Range	1–22	0–20
Mean (Standard Deviation)	4.62 (3.29)	5.52 (4.01)
Continent Where Residing (number/%)		
South America	6 (8%)	5 (5.5%)
North America	4 (5.3%)	5 (5.5%)
Africa	44 (58.7%)	61 (67%)
Asia	16 (21.3%)	16 (17.6%)
Australia	2 (2.7%)	4 (4.4%)
Europe	3 (4%)	
Number of Countries Represented	26	28

Table 2

Summary of Participants' Narrative Comments in Course Evaluations Identifying Positive and Negative Aspects of Courses

Theme	Number of Times Coded
Positive Aspects of Course (352 total)	
Group Interaction	122
Course Content	83
Course Tools (ELearning Platform, CD ROM, Notebooks)	41
Instructor Interaction	40
Course Organization	37
Course Assignments	24
Increased Confidence and Promoted Career Advancement	5
Negative Aspects of Course (205 total)	
Time Constraints (Not Enough Time to Complete Course Requirements)	70
Problems With Course Platform or Structure	43
Complaints Related to Course Assignments	29
Complaints Related to Course Content	24
Complaints Related to Other Students	14
Complaints About Instructors	13
Other	12

Table 3

Responses to Final Program Evaluation Survey

Evaluation Items	Year 1 Mean (SD) N=40	Year 2 Mean (SD) N = 51
1. My participation in the certificate program has enhanced my knowledge about clinical research coordination and management	3.58 (.88)	3.58 (.92)
2. My participation in the certificate program has enhanced my skill in performing my job	3.43 (.87)	3.57 (.92)
3. My participation in the certificate program has contributed to improvement in the research capacity at my site	3.33 (.83)	3.49 (.78)
4. The use of distance education methods was an effective way to offer this certificate program	3.38 (.84)	3.55 (.81)
5. The faculty provided helpful guidance and feedback	3.48 (.85)	3.45 (.92)
6. I would recommend this program to others	3.66 (.87)	3.67 (.91)
7. I achieved my overall program learning goals	3.62 (.57)	3.61 (.57)
8. Notebooks containing hard copies of all course modules and readings	3.73 (.55)	3.67 (.91)
9. CD-ROM with electronic files of course materials and readings	3.63 (.59)	3.57 (.57)
10. Blackboard/Vista Learning Platform discussion boards	3.70 (.52)	3.86 (.35)
11. Blackboard/VISTA Live classroom or chat sessions	3.29 (1.04)	3.54 (1.1)
12. Text Messaging (if you did not participate in this aspect of the course, please mark NA)	3.82 (1.07)	3.94 (1.27)
13. Podcasts	4.00 (1.07)	3.90 (1.02)
14. ePortfolio development	3.47 (.65)	3.80 (.45)
15. Faculty mentoring	3.67 (.53)	3.89 (.51)
16. Networking/communicating with other students	3.54 (.64)	3.86 (.67)
17. Offering capacity building programs at my site	3.50 (.59)	3.73 (.53)

Note: Responses to Items 1–7 were rated on a 4-point Likert scale with 1= Strongly Disagree; 2= Disagree; 3= Agree; 4= Strongly Agree; Responses to Items 8–17 reflected level of satisfaction with the various elements of the courses with 1=Highly dissatisfied; 2=Dissatisfied; 3=Satisfied; 4=Highly Satisfied

Table 4

Changes in Pretests and Posttests Measuring Students' Knowledge of Course Content

Course, Number of Items on Test, and Year Offered	Pretest Mean (SD)	Posttest Mean (SD)	T (df)	Probability
RC1– Year 1	68.37 (18.30)	92.46 (10.97)	10.86 (69)	P<.001
RC1– Year 2	69.48 (14.67)	84.11 (21.54)	4.70 (74)	P<.001
RC2– Year 1	82.94 (12.49)	93.06 (5.88)	7.32 (63)	P<.001
RC2– Year 2	82.85 (10.30)	91.00 (8.98)	6.69 (72)	P<.001
RC3 – Year 1	67.14 (17.63)	87.70 (8.83)	8.56 (58)	P<.001
RC3– Year 2	65.84 (17.34)	85.99 (10.74)	10.26 (72)	P<.001
RC4– Year 1	69.94 (7.39)	75.09 (10.00)	4.01 (58)	P<.001
RC4– Year 2	66.43 (10.07)	83.16 (13.23)	8.35(68)	P<.001

Note: Participants were allowed three attempts to achieve the required grade on the posttest, but most were successful on the first attempt. The scores on the first attempt were used for the t-test analyses.

Table 5

Summary of Capacity Building Activities at Sites

Capacity Building Activities	Total Events Years 1 and 2	Total Participants Years 1 and 2
1. Informed Consent Process	32	378
2. Development of Standard Operating Procedures/Protocols	29	247
3. Recruitment and Community Activities	16	193
4. Needs Assessment/ Site Capacity Building	38	736
5. Data Management - General	8	142
6. Quality Management/Quality Assurance	25	253
7. Study Protocol Specific Training	72	1304
8. Teaching/Learning Process	4	102
9. Good Clinical Practices – General Training	34	754
10. Good Clinical Practices Specific Training	23	442
11. Research Designs/Statistics	8	159
12. Other	19	351
TOTAL	309	5,061

Table 6

Results of Supervisor Evaluations of Program

	Year 1 N= 12		Year 2 N= 9	
Item	**Mean**	**SD**	**Mean**	**SD**
1. The CRM shared lessons learned from the distance education program with other personnel at the site	3.1	.9	3.1	.3
2. The CRM's effectiveness was enhanced as a result of participating in the distance education program	3.5	.5	3.3	.5
3. The research capabilities at our site were improved as a result of the CRM participating in the distance education program	3.3	.6	3.0	.0
4. I would recommend that other CRMs participate in this distance education program	3.5	.1	3.3	.5

Note: Items were rated on a 4-point Likert Scale (1=Strongly Disagree; 2=Disagree; 3=Agree, 4=Strongly Agree).

EXHIBIT 1

Course Titles and Objectives

Research Coordination 1 (RC1) – Overview of Teaching Strategies in Clinical Research (6 weeks)
Discuss basic principles and theories of teaching and learning.
Apply strategies for assessment of learning needs.
Develop learning objectives and prepare an educational program based on an assessment of learning needs.
Evaluate strengths and limitations of a variety of teaching strategies.
Apply strategies for evaluation of educational programs.
Research Coordination 2 (RC2) - Overview of Historical, Ethical, and Cultural Issues in Clinical Research (6 weeks)
Analyze historical, cultural, and ethical influences on clinical research.
Describe critical components of the informed consent process
Discuss good clinical practice guidelines.
Discuss issues related to scientific integrity in clinical research
Research Coordination 3 (RC3) – Overview of Research Methods and Regulatory Processes in Clinical Research (6 weeks)
Identify different types of descriptive and experimental clinical studies.
Identify threats to internal and external validity in clinical studies.
Analyze strategies that CRMs and investigators can use to minimize threats to internal and external validity in clinical studies.
Analyze strategies for regulatory approval of clinical studies.
Research Coordination 4 (RC4) - Overview of Clinical Research Site Operations and Management (12 weeks)
Differentiate the roles of personnel in a clinical study.
Discuss the process for study protocol review and feasibility analyses.
Review sponsor criteria for study site selection and monitoring.
Develop strategies for recruitment, informed consent and retention of study participants.
Analyze the process of ensuring data quality in clinical research
Discuss issues in managing a clinical research site.
Develop standard operating procedures and protocols for ensuring compliance with ethical guidelines for research and preventing or addressing scientific misconduct and conflicts of interest.
Develop and implement a project to enhance team function and leadership in the planning, implementing and evaluating of a clinical trial protocol at the research site.
Research Coordination 5 (RC5) – Issues in Clinical Research (6 weeks)
Identify and discuss current issues in clinical research
Develop individual learning goals and implement project based on these goals.
Develop and present formatted annotated bibliographies of literature search findings
Discuss issues in clinical research management based on shared findings within the course community.